T-082 P.001



ENWICK & WEST

SAN FRANCISCO OFFICE | EMBARCADERO CENTER WEST 275 BATTERY ST., SUITE 1500 | SAN FRANCISCO, CA 94111 TEL 415.875.2300 | FAX 415.281.1350 | WWW.FENWICK.COM

FACSIMILE TRANSMISSION

CONFIDENTIAL

7/21/04 DATE:

ATTORNEY DOCKET No: 23714-799245

Name	FAX No.	PHONE NO.
USPTO GAU 1644 Examiner Ewoldt	(703) 872-9306	

FROM:

Susan T. Hubl, Ph.D.

PHONE:

(415) 875-2316

Patent Agent

FROM-FENWICK&WEST SF

ORIGINAL WILL NOT FOLLOW NUMBER OF PAGES WITH COVER PAGE:

MESSAGE:

US Patent Application Ho: 10/773,356

CAUTION - CONFIDENTIAL

THE INFORMATION CONTAINED IN THIS FACSIMILE MESSAGE IS PRIVILEGED AND CONFIDENTIAL INFORMATION INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY NAMED ABOVE OR THEIR DESIGNEE. IF THE READER OF THIS MESSAGE IS NOT THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION OR COPY OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR PLEASE IMMEDIATELY NOTIFY US BY TELEPHONE AND RETURN THE ORIGINAL MESSAGE TO US AT THE ABOVE ADDRESS VIA THE U.S. POSTAL SERVICE. THANK YOU.

IF YOU DO NOT RECE	EIVE ALL OF THE PAGES, OR IF THEY A	RE NOT CLEAR,
PLEASE CALL	AT	AS SOON AS
	POSSIBLE.	

0001/PTO Rev. 10/95	U.S. Department of Patent and Trade	Commerce nark Office	Арр	xication Number	10/773,356	
			Filir	ig Date	FEBRUAR	r 5, 2004
TRANS	MITTAL FOR	М	Firs	t Named Inventor	WEINER	
(to be used for all co	orrespondence during po led application)	andency of	Gro	oup Art Unit Number	1644	
	•		Exa	ıminer Name	EWOLDT	
Total Number of Pag	es In This Submission	7	Atto	omey Docket Number	23714-7992	½/US
	MNOL	OCUPEC	(0)	heck all that apply	(r)	
		OSURES	(S)	Issue Fee Transi		
	Form (in duplicate) ck Enclosed			Letter to Chief Di		
Return Receipt	Postcard			Formal Drawing(s):	
	otice to File Missing Par	ts		[] Sheet(s	s) of Figure(s) [1
Assignment & F	Recordation Cover Shee	et .	ŀ	Appeal Commun	nication to Board	of Appeals and
Declaration				Interferences	_	
Power of Attom	еу			Appeal Commun	nication to Group) of)
Application Date	a Sheet		Ì	(Appeal Notice,		
Information Dis	closure Statement & P1	O/SB/08A		Certified Copy of	Priority Docum	ent(5)
_	(5 [pp)		ļ	After Allowance	Communication	to Group
	rrected Filing Receipt			FAX COVER S	HEET	
Request for Co	rrection of Recorded As	signment		∐		
	esponse: [] Page(s)					
After						
Status Reques						
, 		Haumot I		<u> </u>		
Revocation and	d Substitute Power of A	пошей		L		
REMARKS:				•		
	SIGNA	TURE OF	ΑT	FORNEY OR AGE	NT	
		n It				
Signature:					Dated:	7/21/04
Attomey/Reg. No.:	SUSANT. HUBL, PI	I.U., PAIEN	ı AG	ENT/ REG NO. 47,668	54.66.	1-1-1-
				NAME TO A NICEAR	SCION	
	CERTIFIC	ATE OF I	-AU	SIMILE TRANSMIS	nitted on the date s	hown below via facsimile
I hereby certify that this to: Commissioner for f	correspondence, including atents at the facsimile num	IDEI IIIQICAGG	<u></u> Λ	MIGG SPOAC' 19 ACTUR RELIGIO		
Signature:	Mum	1 1-37	M		Dated:	2/2/154
Typed or Printed Na	me: SUSAN T. HU				DATEG:	7/21/01
Escsimila Number:	İ	1-703-872-	9306	. <u></u>		·

-Millian Bon Demons

CHICAL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPL	YOU	·TW
AFFL		MAT.

WEINER ET AL

10/773,356

FILING DATE:

APPLICATION NO.:

FEBRUARY 5, 2004

TITLE:

T CELL VACCINATION FOR THE TREATMENT OF

MULTIPLE SCLEROSIS

EXAMINER:

EWOLDT

GROUP ART UNIT:

1644

ATTY, DKT, NO.:

23714-07992US

ALLI, DAL, NO.	25/11 0755200				
	CERTIFICATE OF FACSIMILE TRAN	NSMISSION			
hereby certify that this correspondence, including the enclosures identified above, is being transmitted on the date shown below via facsimile to Commissional for					
Putents at the facsimile number indicated below.					
Signature:	Sum Hobe				
	SUSAN T. HUBL	Dated:	7/21/04		
Typed or Printed Name:	DUDIET I, MORE		- 1 - 1		
Facsimile Number:	1-703-872-9306				

MAIL STOP AMENDMENT COMMISSIONER FOR PATENTS P.O. BOX 1450 ALEXANDRIA, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT Under 37 CFR §§ 1.56 and 1.97-98

SIR:

Pursuant to the provisions of 37 CFR §§ 1.56 and 1.97-98, enclosed herewith is modified form PTO/SB/08A listing references for consideration by the Examiner.

The filing of this Information Disclosure Statement shall not be construed as a representation regarding the completeness of the list of references, or that inclusion of a reference in this list is an admission that it is prior art or is pertinent to this application, or that a search has been made, or as an admission that the information listed is, or may be considered to be, material to patentability, or that no other material information exists, and shall not be construed as an admission against interest in any manner.

This Information Disclosure Statement is being filed:

- within three months of the filing date of the application, or date of entry into the national stage of an international application, or before the mailing date of a first office action on the merits, whichever event last occurred;
- This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior application No. 09/156,509 filed on SEPTEMBER 17, 1998, and the references cited

23714/07992/SF/5125123.1 07/21/04

PATENT

therein are hereby referenced, but are not required to be provided in this application under 37 CFR § 1.98(d).

+14153950879

Applicant submits that no fee is required for the consideration of this Information \boxtimes Disclosure Statement.

Consideration of the listed references and favorable action are solicited.

Respectfully submitted, LESLIE WEINER ET AL

By: Mun Hubl, Patent Agent, Reg. No.: 47,668

Fenwick & West LLP Silicon Valley Center 801 California Street Mountain View, CA 94041

Tel.: (415) 875-2316 Fax.: (650) 938-5200

			U.S. PAT	ENT DOCUMENTS
	Т	Document No.		
Examiner Initials"	Cite No.1	Number - Kind Code ² (If known)	Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
THOMAS	A1	US-5,849,886	12-15-1998	MAATTA ET AL

			FOREIGN PA	TENT DOCUMENTS	
		Foreign Patent Document			
Examiner Initials*	Cite No.1	Country Code ³ - Number Kind Code ⁵ (If known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	
	 	WO 91/015225	17-10-1991	BRIGHAM AND WOMEN'S HOSPITAL ET AL	
	 -	WO 90/010449	20-09-1990	COHEN ET AL	
		WO 03/024393 A2	12-09-2002	OPEXA PHARMACEUTICALS ET AL	

		OTHER REFERENCES - NON-PATENT LITERATURE DOCUMENTS	
xaminer Initials"	Cite No.1	OTHER REFERENCES - NON-PATENT Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, include name of the author (in CAPITAL LETTERS), volume-issue number(s), publisher, city and/or country where journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T⁵
		ACHA-ORBEA, H., et al., "Limited heterogeneity of T cell receptors from lymphocytes medicating autoimmune encephalomyelitis allows specific immune intervention," <u>Cell</u> , (1988) 54: 263-273	
		BEN-NUN, A. ET AL. "The autoimmune reactivity to myelin oligodendrocyte glycoprotein (MOG) in multiple scienosis is potentially pathogenic: effect of copolymer 1 on MOG-induced disease." <u>J. Neurol</u> (1996) 243[Suppl 1]:S14-S22	
		BEN-NUN, A., ET AL., "Restricted T-Cell receptor Vβ gene usage by myelin base protein-specific T-Cell clones in multiple sclerosis: Predominant genes vary in individuals," <u>Proc. Nat. Acad. Sci USA</u> (1991) 88: 2466-2470	
	 	BOURDETTE, D.N., ET AL., "Immunity to TCR peptides in multiple sclerosis. I. Successful immunization of patients with synthetic Vβ5.2 and Vβ6.1 CDR2 peptides," <u>J. Immunol.</u> (1994) 152:2510-2519	
		CHOU, Y.K., ET AL., "Immunity to TCR peptides in multiple sclerosis. II. T Cell Recognition of Vβ5.2 and Vβ6.1 CDR2 peptides," J. Immunol. (1994) 152:2520.2529	
		COHEN, PL. "Systemic autoimmunity" from <u>Fundamental Immunology</u> . (1999) pages 1067 and 1083. William E. Paul, editor, Lippencott-Raven, Publishers.	

Examiner Signature	Date Considere	ed

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609.

Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁴Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO	Complete if Known			
	Application No.	10/773,356		
RMATION DISCLOSURE	Filing Date	February 5, 2004		
EMENT BY APPLICANT	First Named Inventor	Weiner et al.		
	Art Unit	1644		
54Nt 7/21/04	Examiner Name	EWOLDT		
2 of 3	Attorney Docket Number	23714-07992/US		
	Substitute for form 1448APPTO RMATION DISCLOSURE EMENT BY APPLICANT 5'84 7/21/04	Application No. Filling Date First Named Inventor Art Unit SENT 7/21/04 Examiner Name	Application No. 10/773,356 Filing Date February 5, 2004 First Named Inventor Weiner et al. Art Unit 1644 Examiner Name EWOLDT	

		OTHER REFERENCES - NON-PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, include name of the author (in CAPITAL LETTERS), title of the author number(s), publisher, city and/or country where	T .
examinēr Initials"	Cité No.1	include name of the author (in CAPITAL LETTERS), the or the allude (which approximate, has on the author (in CAPITAL LETTERS), use or the allude (which allude (which allude), has one include (allude). In the allude (which allude) and in the allude (which allude) and in the allude (which allude) are allude (which allude). In the allude (which allude) are allude (which allude) are allude (which allude) are allude (which allude). In the allude (which allude) are allude (which allude) are allude (which allude). In the allude (which allude) are allude (which allude) are allude (which allude). In the allude (which allude) are allude (which allude). In the allude (which allude) are allude (which allude). In the allude (which allude) are allude (which allude). In the allude (which allude) are allude (which allude). In the allude (which allude) are allude) are allude). In the allude (which allude) are allude) are allude (which allude) are allude). In the allude (which allude) are allude) are allude (which allude) are allude). In the allude (which allude) are allude) are allude). In the allude (which allude) are allude) are allude). In the allude) are allude) are allude). In the allude) are allude) are allude). In the allude) are allude) are allude) are allude). In the allude) are allude) are allude) are allude). In the allude) are allude) are allude) are allude) are allude). In the allude) are allude) are allude) are allude) are allude) are allude). In the allude) are allude) are allude) are allude) are allude) are allude) are allude). In the allude) are allude). In the allude) are allude) are allude) are allude) are allude) are allude) are al	T ⁶
		CORREALE, J., ET AL. "Isolation and characterization of CD8+ T-cell clones (TCCs) that recognize autologous-activated CD4+ TCCs from chronic progressive multiple sclerosis (MS) patients: implications for immunoregulation in MS," Neurology, (February 1996) 46; Suppl. S, p. A280	
		CORREALE, J. ET AL. "T-cell vaccination in secondary progressive multiple sclerosis." <u>Journal of Neuroimmunology</u> . (2000) 107:130-139.	
		GOLD, D.P., ET AL., "Results of a phase 1 clinical trial of a T-cell receptor vaccine in patients with multiple sclerosis. II. Comparative analysis of TCR utilization in CSF T-cell populations before and after vaccination with a TCR Vβ6 CDR 2 peptide, J. Neuroimmunol., (1997) 76 pp. 29-38.	
		HAFLER, D.A., ET AL. "T cell vaccination in multiple sclerosis: A preliminary report," Clin. Immunol Immunopath. (1992) 52(3), pp. 307-313	
		HOWELL, M.D., ET AL. "Vaccination against experimental allergic encephalomyelitis with T cell receptor peptides." Science, (1989) 245:568-670.	
		LIBLAU, R., ET AL., "T cell response to myelin basic protein epitopes in multiple sclerosis patients and healthy subjects," Eur. J. Imunol., (1991) 21:1391-1395.	
		LOHSE, A.W., ET AL. "Control of experimental autoimmune encephalomyelitis by T cells responding to activated T cells," <u>Science</u> (1989) 244:820-822.	
		MEDAER, R., ET AL. "Prospects for T cell vaccination in multiple sclerosis," <u>BioDrugs.</u> (1997), 8:1-5.	
		MILLER, STEPHEN D., ET AL. "The immunopathogenesis and regulation of T-cell mediated demyelinating disease." https://mmunology.com/reday . (1994) 15:356-361.	
		MORELAND, L., ET AL. "Vaccination against rheumatoid arthritis," BioDrugs, (1997) 8:87-95.	
		STINISSEN, P., ET AL. "Vaccination with autoreactive T cell clones in multiple sclerosis: Overview of Immunological and clinical data," <u>Journal of Neuroscience Research</u> (1996) 45:500-511.	
	-	VAN DER AA ET AL. "T cell vaccination in multiple scierosis patients with autologous CSF derived activated T cells; results from a pilot study." Clin. Exp. Immunof. (2003) 131:155-168.	
		VAN LAAR, J., ET AL. "Effects of inoculation with attenuated autologous T cells in patients with rheumatoid arthritis." <u>Journal of Autoimmunity</u> , (1993) 6:159-167	

F	Date
Examiner	Considered
Signature	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609.

Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

^{&#}x27;Applicant's unique citation designation number (optional). 'See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 'Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 'For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 'Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 'Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO		Complete if Known			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			Application No.	10/773,356	
			Filing Date	February 5, 2004	
			First Named Inventor	Weiner et al.	
			Art Unit	1644	
sout:	7/21/0	r4	Examiner Name	EWOLDT	
1 3 1	of	3	Attorney Docket Number	23714-07992/US	
	RMATION EMENT B	RMATION DISCLEMENT BY APP	SENT 7/21/04	RMATION DISCLOSURE Filing Date First Named Inventor Art Unit Examiner Name	RMATION DISCLOSURE Filing Date February 5, 2004 First Named Inventor Weiner et al. Art Unit 1644 Examiner Name EWOLDT

		OTHER REFERENCES - NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cits No. ^T	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magaz journal, serial, symposium, catalog, etc.), date, page(s), volume-lesue number(s), publisher, city and/or country where published			
		VANDENBARK, A.A., ET AL. "T Cell receptor peptides in treatment of autoimmune disease: rational and potential," J. Neurosci. Res., (1996) 43:391-402			
		VANDENBARK, A.A., ET Al. "Immunization with a synthetic T-cell receptor V-region peptide protects against experimental autoimmune encephalomyelitis, " <u>Nature</u> (1989) 341:541-544			
,		WEINER, L., ET AL., "Isolation and characterization of CD8+ and garmna-delta T cells specific for autologous autoreactive CD4+ T cell clones from multiple sclerosis patients and healthy control subjects," Neurology, (March 1997), 48 (3) Suppl. 2, pp. A59-A60			
		ZHANG, J., ET AL. "T-cell vaccination in autoimmune diseases – from laboratory to clinic," <u>Human Immunol.</u> (1993) 38, pp. 87-96			
		ZHANG, J., J., ET At., "MHC-restricted depletion of human myelin basic protein-reactive T cells by T cell vaccination." <u>Science</u> , (1993) 261:1451-1454			
		ZHANG, J., ET AL. "Myelin basic protein-reactive T cells in multiple sclerosis: pathologic relevance and therapeutic targeting." Cvtotechnology (1994) 16:181-817			
		ZHANG ET AL. In vivo clonotypic regulation of human myelin basic protein reactive T cells by T cell vaccination." <u>Journal of Immunicov</u> ((1995) 155:5868-5877			
		ZHANG, J. "Multiple Sclerosis: Perspectives on Autoimmune Pathology and Prospects for Therapy," <u>Current Neurology</u> (1995) 15:115-155			

23714/07992/SF/5122822.1

Examiner Signature	1	Date Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that leaved the document, by the two-letter code (WIPO Standard ST.S). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Skind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.